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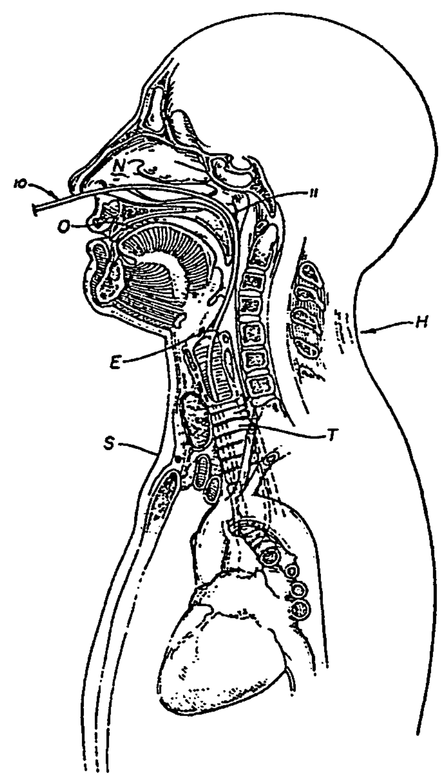
(54) Title: METHOD AND APPARATUS FOR MEASURING ARTERIAL BLOOD FLOW

(57) Abstract

Blood flow in the aorta and pulmonary artery of a mammal, most typically a human, is measured volumetrically by a non-invasive, ultrasound method and apparatus. The method comprises placing a piezoelectric ultrasound transducer in the trachea in great proximity to the aorta or pulmonary artery by passage through the oral or nasal cavity past the epiglottis and into the trachea or by passage through the surgical opening into the trachea in the case of patients who have had a tracheotomy. Ultrasound waves are transmitted toward the path of flow of blood in the artery. Reflected waves are received. The average Doppler frequency difference between transmitted and received waves is measured. The cross-sectional size of the artery is measured. Blood flow rate is determined from the measurements. The apparatus comprises a tracheal tube (11) or probe with one or two transducers (21, 22) mounted at one end of the tube. The transducer(s) is (are) disposed to transmit ultrasound in selected directions. Electrical conductors (24, 25, 26, 27) extend from the transducers the length of the probe.



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METHOD AND APPARATUS FOR MEASURING ARTERIAL BLOOD FLOW

Field of Invention

Measurement of cardiac output is crucial in the care of critically ill patients such as patients with multiple trauma, patients in overwhelming sepsis, and patients with acute myocardial infarction. In the case of patients with acute myocardial infarction, there is a worsening prognosis with decrease in cardiac output. Knowledge of the cardiac output provides information useful in determining the clinical state of a given patient and in rationally planning therapy for the patient. Such information is not contained in the usually measured vital signs. For example, a low mean arterial pressure with elevated pulse does not adequately distinguish between cardiogenic and septic shock, the treatments for which are quite different. Consequently, a method that distinguishes between cardiogenic and septic shock would be important in planning appropriate therapy. The measurement of cardiac output, in this case, would provide valuable information that would allow an appropriate diagnosis to be made.

Prior Art

The importance of knowing cardiac output has led to many methods for its determination. The most commonly used method in widespread clinical use is thermodilution. In the thermodilution method a catheter is placed into the central venous circulation, usually by percutaneous entry into the internal jugular or subclavian vein. A balloon at the end of the catheter is inflated, and the normal flow of blood is employed to direct the tip of the catheter into the pulmonary artery.

Measurement of cardiac output is made by observing the dissipation of a temperature pulse, usually a bolus of iced sterile water or saline solution. As is evident, the method cannot be used without invasion of the vascular tree. Indeed, the catheter is threaded through the heart and the heart valves. Flow direction is not entirely reliable. In certain patients access to the pulmonary artery is impossible. During placement of the catheter cardiac arrhythmias are not uncommon. Other complications include sepsis, thrombosis of the central veins, emboli, and fatal rupture of the pulmonary artery. Other disadvantages of the technique include lack of continuous information about the cardiac output and chance location of the catheter, such as in an unfavorable pulmonary artery branch, with erroneous values for the cardiac output. Analysis of the error inherent in the measurement of blood flow by thermodilution has revealed a standard deviation of 20-30%.

Measurement of cardiac output has also been done by the indocyanine green dye technique, which suffers from several disadvantages. The technique is cumbersome, it requires the placement of an arterial catheter, is not accurate at low levels of cardiac output and is difficult to use for repeated measurements in the same patient. Complications include catheter site hematoma, sepsis from the catheter, thromboses of the artery containing the indwelling catheter, and pseudoaneurysm formation at the site of arterial puncture.

The Fick method is based on the measurement of oxygen consumption. It is best used in awake,

alert, stable patients not requiring respiratory support on a ventilator. The method requires invasion of the pulmonary artery in order to obtain samples of mixed venous blood for determination of the oxygen content. Like the indocyanine green dye technique, an arterial catheter must be placed for sampling of arterial blood for oxygen content with the disadvantages mentioned above.

Transcutaneous ultrasound has also been used. Ultrasound transducers are placed externally on the body at the suprasternal notch. Under the most sanguine circumstances, at least 10% of patients cannot have their cardiac outputs measured in this way. Many difficulties with this approach have been reported: repeated measurements may lead to varying location of the sample volume that is scanned, there are changes in the angle of intersection of the ultrasound beam with the axis of the vessel, capability for continuous measurement of the cardiac output is not available, and other major thoracic vessels may interfere with the Doppler ultrasound signals. Further, the method is not feasible in many important clinical settings in which the patients are not cooperative or are in the operating room, where the suprasternal notch may not be accessible.

Because of these difficulties, an implantable, removable Doppler ultrasound device for measurement of the cardiac output has been developed for direct attachment to the aorta. The device requires a major, operative, invasive intervention, such as splitting the sternum or removal of a rib to enter the chest cavity, for placement of the device directly on the wall of the aorta. Removal of the device also requires surgical

intervention. If the device were to be lost in a major body cavity, a major surgical procedure would be required.

Measurement of cardiac output by continuous or single breath, gas-washout has been attempted, but is not used in standard clinical medicine. Such methods require many approximations of lung function in modeling the system. Time consuming numerical analysis is required. In one study, measurement of cardiac output in anesthetized patients using argon and freon during passive rebreathing was shown to provide lower cardiac outputs than a simultaneously performed Fick determination. The authors concluded that the method caused significant disturbances of hemodynamics and was therefore not suitable for widespread use.

Indirect measurements include the pulse, blood pressure, and urine output, but these measurements are not specific for cardiac output. For example, in the presence of acute renal failure, urine output cannot be correlated with perfusion of major organs.

The foregoing prior art techniques, including Doppler ultrasound techniques, are described more particularly in the following prior art publications:

1) D. W. Baker, "Pulsed Ultrasonic Doppler Blood-Flow Sensing", IEEE Transactions on Sonics and Ultrasonics, Vol. SU-17, No. 3, 170-185, July 1970.

2) C. P. Jethwa, Mostafa Kaveh, G. R. Cooper, and F. Saggio, "Blood Flow Measurements Using Ultrasonic Pulsed Random Signal Doppler System", IEEE Transactions on Sonics and Ultrasonics, 1-11, January 1975.

3) L. L. Huntsman, Emmeram Gams, Curtis C. Johnson and Eugene Fairbanks, "Transcutaneous Determination of Aortic Blood-flow", American Heart Journal, Vol. 89, No. 5, 605-612, May 1975.

4) F. H. Kohanna and J. N. Cunningham, "Monitoring of Cardiac Output by Thermodilution after Open Heart Surgery", The Journal of Thoracic and Cardiovascular Surgery, Vol. 73, No. 3, 451-457, March 1977.

5) John R. Darsee, David F. Walter, Donald O. Nutter, "Transcutaneous Doppler Method of Measuring Cardiac Output", The American Journal of Cardiology, Vol. 46, 613-618, October 1980.

6) C. P. H. Heneghan and M. A. Branthwaite, "Non-Invasive Measurement of Cardiac Output During Anaesthesia", British Journal of Anaesthesia, Vol. 53, 351-355, 1981.

7) L. L. Huntsman, D. K. Stewart, S. R. Barnes, S. B. Franklin, J. S. Colocousis, and E. A. Hessel, "Noninvasive Doppler Determination of Cardiac Output in Man, Clinical Validation", Circulation, Vol. 67, No. 3, March 1983.

8) B. A. Keagy, C. L. Lucas, H. S. Hsiao and B. R. Wilcox, "A Removable Extraluminal Doppler Probe for Continuous Monitoring of Changes in Cardiac Output", Journal of Ultrasound Medicine, 2:357-362, August 1983.

9) C. J. Hartley and J. S. Cole, "An Ultrasonic Pulsed Doppler System for Measuring Blood Flow in Small Vessels", Journal of Applied Physiology, Vol. 37, No. 4, October 1974.

In the patent art, Tickner, U.S. Patent No. 4,316,391 discloses an ultrasound technique

for measuring blood flow rate. Colley et al., U.S. Patent No. 4,354,501, discloses an ultrasound technique for detecting air emboli in blood vessels. Numerous patents disclose catheters or probes, including Calinog, U.S. Patent No. 3,734,094, Wall, U.S. Patent No. 3,951,136, Mylrea et al., U.S. Patent No. Re. 31,377, Perlin, U.S. Patent Nos. 4,304,239; 4,304,240 and 4,349,031, Colley et al., U.S. Patent No. 4,354,501 and Furler, U.S. Patent No. 4,369,794.

An ideal method would provide for the determination of the cardiac output in a way that is accurate, noninvasive, continuous, inexpensive and suitable for use in those patients whose cardiac output measurement is most critical. The present invention substantially meets such requirements.

Summary of Invention

The primary object of the invention is to provide a method and apparatus for continuously and accurately measuring cardiac output in a major discharge artery of a mammalian heart, most notably the human heart, without invasion of any closed anatomical cavity or system and without surgery.

The method of the invention comprises placing a sound transducer in great proximity to the aorta or pulmonary artery of the heart of the mammal by passing a probe carrying the transducer into the trachea and transmitting ultrasound waves from the transducer toward the path of flow of blood in the artery. The probe can be passed through the nasal or oral cavity, past the epiglottis into the trachea or, in the case of patients who have had a tracheostomy, directly into the trachea through the surgical

Figure 3 is a horizontal sectional view of the trunk of a human taken at the level of the tracheal bifurcation and shows the close relationship between the trachea and the aorta and the pulmonary arteries.

Figure 4 is a perspective view of the probe of the present invention with one end cut away in axial section to show the transducer mounting and orientation with respect to the axis of the tube.

Figure 5 is a schematic view of the trachea and the aorta and shows the location and orientation of the probe and transducers with respect to the path of flow of blood in the aorta.

Figure 6 is a schematic view and block diagram showing the orientation and relationship of the transducers. The electrical conductors running the length of the tube to the ultrasound generating and receiving device are also shown.

Description of Preferred Embodiment

Apparatus

The apparatus of the preferred embodiment consists of a probe with a piezoelectric transducer mounted at one end and electrical conductors extending the length of the probe for connection to conventional directional pulsed or continuous wave Doppler ultrasound hardware, such as that described by Hartley et al. in the Journal of Applied Physiology, October 1974, and by Keagy et al. in the Journal of Ultrasound Medicine, August 1983. Modifications to the signal output can be made to display blood flow volume rate, aorta or other vessel diameter, blood velocity and other selected displays.

The probe 10 is shown in Figures 1,

opening. The reflected ultrasound waves are received by the transducer and the average Doppler frequency difference between the transmitted waves and the reflected waves is measured. The cross-sectional size or area of the artery at the point of ultrasound reflection is measured and the volumetric blood flow rate is determined from such measurements. The transducer is oriented to transmit and receive ultrasound waves in a direction within the range of 10° - 80° with respect to the direction of the path of flow of blood in the artery.

The apparatus of the invention is a trachael probe comprising a flexible tube of sufficient length to extend from the oral or nasal cavity or from a surgical trachael opening, through the trachea to the bifurcation thereof, with an ultrasound transducer mounted on the tube in proximity to one end and disposed to transmit in a direction within the range of 10° - 80° with respect to the axis of the tube. Electrical conductors extend from the transducer the length of the tube. A second transducer can also be mounted on the tube.

Description of Drawings

Figure 1 is a front to back vertical sectional view of the upper portion of the human body showing the nasal and oral cavities and the pathway through the trachea to the bifurcation thereof. The heart is shown in left lateral or side view. The trachea probe of the invention is shown in position in the trachea with the transducer(s) in great proximity to the aorta.

Figure 2 is a front view of the aorta, the trachea, including the bifurcation thereof, and the esophagus and shows the close relationship between the trachea and the aorta.

4, 5 and 6. Probe 10 consists of flexible plastic tubing 11 roughly three to four feet long and about one-fourth inch in outside diameter. The length must be sufficient to extend from outside the body to the vicinity of the heart through the trachea entering either through the nasal or oral cavity, or through a surgical opening in the case of patients who have had a tracheotomy.

In the preferred embodiment, two piezoelectric transducers or chips 21 and 22 are mounted to the exterior of tube 11 at one end in a mounting medium 23. Transducer 21 is used to collect Doppler data for velocity calculation and transducer 22 is used to collect data for calculation of the diameter of the artery at the point of velocity measurement, although data for diameter measurement can also be collected, though less critically, using transducer 21. Electrical conductors 24, 25, 26 and 27 extend the length of tube 11 for connection to the conventional Doppler ultrasound hardware 28. Piezoelectric transducers 21 and 22 are directional in ultrasound transmission and are oriented as shown in Figure 6. Transducer 21 is oriented to transmit and receive ultrasound in a direction 45° with respect to the axis of tube 11, and transducer 22 is oriented to transmit and receive ultrasound in the same plane (i.e. in the plane defined by the axis of tube 11 and the direction of ultrasound transmission from transducer 21) but 90° with respect to the axis of tube 11. The angle of ultrasound transmission from transducer 21 with respect to the axis of tube 11 is designated ϕ (See Figure 6). In the preferred embodiment ϕ is 45° but the angle may vary in the range of 10° - 80°. Angles less than 10° are not suitable because of the lack of ability

to intercept an offset flow path substantially parallel to the axis of tube 11 (which is necessary in the use of the method described in greater detail below), and angles between 80° and 90° are not suitable because the Doppler shift is nonexistent or too small to be useful when the ultrasound waves are reflected by a flow path perpendicular to the direction of the ultrasound transmission. It should also be recognized that piezoelectric transducer 21 can be directed in either direction of the axis of tube 11, i.e., either toward or away from transducer 22, resulting in ultrasound transmission either generally up-stream or generally down-stream of the blood flow path in the artery.

The spacing or distance between transducer 21 and transducer 22 is a function of the angle and the diameter of the vessel, such as the aorta or pulmonary artery, in which the blood flow measurement is being made, so that the diameter data utilizing transducer 22 and the velocity data utilizing transducer 21 are taken in the same plane across the artery. This insures that the volume computation (velocity x cross-sectional area) is accurate. More specifically, the distance, D, (See Figure 6) is the estimated diameter, d_e, of the vessel at the point of measurement (transducer 22) divided by 2 times the tangent of ϕ, or

$$D = \frac{d_e}{2 \tan \phi}.$$

In the case in which ϕ is 45°, as in the preferred embodiment, the distance, D, between transducers is half the estimated diameter (or the radius) of the vessel at the point of diameter and velocity

measurement.

Electrical conductors 24, 25, 26 and 27 extend the length of tube 11 and must be capable of transmitting ultra high frequency electrical signals (up to 20 mega Hertz) without significant attenuation. For ease of connection and disconnection of conductors 24-27 to the conventional Doppler ultrasound hardware 28, an electrical connector such as that disclosed in the Furler patent (4,369,794) can be used.

The foregoing is a description of the preferred embodiment of the tracheal probe 10 that comprises the apparatus of the present invention. A description of the preferred embodiment of the method follows.

Method

An understanding of the method of the present invention requires some understanding of mammalian anatomy and in particular an understanding of the human anatomy, which is shown in pertinent portion in Figures 1, 2 and 3. The method is based on the step of locating the ultrasound transducers 21 and 22 in great proximity to the arterial vessel in which blood flow is to be measured, most typically the aorta of a human, without surgery or other invasive techniques. The method relies on the anatomical discovery or fact that the aorta and pulmonary artery are located adjacent the trachea just above the bifurcation thereof, and that a transducer placed in the trachea can be directed toward the selected artery and accurate blood flow measurements made without significant interference. With reference to Figures 1, 2 and 3, access to the trachea, T, of a human, H, can be had in accordance with standard medical practice through the nasal cavity,

N, or the oral cavity, O, past the eppiglotis, E, and into the trachea, T. Access can also be had through a surgical opening at the suprasternal notch, S, in the case of patients who have had a tracheotomy. The aorta, A, and the pulmonary artery, PA, are located in great proximity to the trachea, T, just above the bifurcation, as best seen in Figures 2 and 3.

Consequently, a transducer or transducers placed in the trachea as shown in Figure 1 can be directed to transmit and receive ultrasound waves through the wall of the trachea and through the wall of the aorta or the pulmonary artery to be reflected by the blood flowing in the selected artery and, due to the movement of the blood, cause a Doppler shift in the frequency of the reflected waves as compared to the frequency of the transmitted waves. The ultrasound waves are also reflected by the near and far walls of the artery and such reflection can be used for diameter measurement of the artery.

In accordance with the method of the invention, probe 10 is placed to locate transducers 21 and 22 in the trachea, T, pointing toward the selected artery, such as the aorta, A, as shown in Figure 5. The position of probe 10 and transducers 21 and 22 can be adjusted until the maximum Doppler shift is obtained and the position can also be checked or confirmed by X-rays to insure placement for optimum data collection. In general, transducers 21 and 22 should be located just above the tracheal bifurcation and directed toward the selected artery, such as the aorta (See Figure 5).

In accordance with the methods of the preferred embodiment, after proper placement

of probe 10 and connection with the electrical hardware 28, ultrasound signals are generated and the Doppler shift is measured for velocity calculation and data for calculating the diameter of the artery is also collected. These data are used to determine the volumetric rate of blood flow in accordance with the following example.

The average flow velocity $\overline{V}$, of the blood at the point of ultrasound reflection can be determined using the formula:

$$\overline{V} = \frac{C \quad f}{2f_o \text{ Cos } \theta}$$

in which:

$\overline{V}$ = average flow velocity,

C = velocity of sound in the medium (human tissue or blood),

Δf = the average Doppler frequency difference or shift,

θ = the angle between the direction of the transmitted and received waves and the path of flow (velocity vector) of the blood, and

f_o = the ultrasonic carrier frequency (the frequency of transmission).

<u>Example of Calculation</u>

Let:

$C = 1.55 \times 10^5$ cm/sec [Constant for tissue and blood]

$\Delta f = 1.5 \times 10^3$ Hz [Measured by Doppler ultrasound]

$f_o = 10 \times 10^6$ Hz [Assumed primary design frequency], and

$\theta = 45°$ (Cos = 0.7071)

Then:

$$\bar{V} = \frac{(1.55 \times 10^5 \text{ cm/sec}) \ (1.5 \times 10^3 \text{ Hz})}{2 \ (10 \times 10^6 \text{ Hz}) \ (0.7071)}$$

$\bar{V} = 16.4$ cm/sec [Blood velocity]

The volumetric flow rate, Q, can be determined as follows:

$$Q = \bar{V}A$$

in which:

Q = Volumetric flow rate
$\bar{V}$ = Average flow velocity
A = Cross sectional area at the point of velocity measurement

<u>Example of calculation</u>

Let:

$\bar{V} = V = 16.4$ cm/sec

$A = \pi r^2$ with $r = 1.25$ cm

[d-measured by ultrasound, $r = \frac{d}{2}$]

Then:

$Q = 16.4$ cm/sec X 4.909 cm^2

$Q = 80.7$ cm^3/sec or 4.84 liters/minute

In the determination of the area, A, of the artery, transducer 22 is used to collect ultrasound transmission and reflection data from which diameter calculations can be made in conventional manner. For this purpose, transducer 22 is spaced from transducer 21 a distance, D, equal to the estimated diameter, d_e of the artery at the point of measurement divided by 2 times the tangent of ϕ so that ultrasound transmissions and reflections from transducer 22 for diameter calculation intersects the velocity ultrasound transmission and reflections from transducer 21 at the center of the artery. Thus the diameter measurement is taken at the point of registration

of the average mean velocity of flow in the artery so that the volume calculation is accurate. It should also be mentioned that, for the purpose of calculating the cross sectional area of the artery, the area is assumed to be circular, as is apparent in the foregoing example.

It should be noted that angle ϕ is fixed at the time the transducers are mounted on tube 11, assuming no flexing of tube 11 between transducers 21 and 22. In the preferred embodiment the angle ϕ is 45°, although as stated above it may range from 10° - 80°. Assuming placement of tube 11 in position in the trachea with its axis parallel to the path of flow, P, of blood in the artery in which the measurement is to be taken, the angle θ (the angle between the direction of ultrasound transmission from transducer 21 and the flow path, P, of blood in the artery) would be the same as the angle ϕ . It is not always possible, however, to locate tube 11 with its axis precisely parallel to flow path, P. If not positioned parallel to flow path, P, angle θ will not be the same as angle ϕ and, if assumed to be the same unnecessasry error will be introduced into the calculation of velocity, $\bar{V}$. To obtain a more accurate value for θ, the following formula can be used:

$$\theta = \mathrm{Cos}^{-1}\frac{r_1^2 - r_1 r_2 \mathrm{Cos}\,\phi}{r_1\sqrt{r_1^2 + r_2^2 - 2r_1 r_2 \mathrm{Cos}\,\phi}}$$

in which:

r_1 = range or distance to artery centerline for transducer 21

r_2 = range or distance to artery centerline for transducer 22

ϕ = the angle between transducers 21 and 22.

In the foregoing description two transducers 21 and 22 are disclosed, one for the velocity measurement and one for the diameter measurement. Both the velocity data and the diameter data can be collected using only transducer 21. In such a case the velocity determination is made as described above, and the diameter determination is made by calculating the distance of the hypotenuse, d_h, across the artery in the direction of transmission from transducer 21, and calculating the diameter, d, as the hypotenuse times the sin θ i.e., $d = d_h \sin \theta$. The disadvantage in this procedure is that the diameter determination is not made at the intersection of the ultrasound transmission with the center of the artery, and θ must be assumed to be the same as ϕ, which results in some lack of precision in the velocity and volume calculations. Nevertheless, determinations using one transducer only are accurate enough to be useful.

In addition to measuring arterial blood flow rate, the foregoing method can be used during Cardio Pulmonary Resucitation (CPR) to determine the effectiveness of CPR; to determine blood acceleration as well as flow rate; to obtain a blood velocity profile across the artery, such as the aorta, by range gating; to measure the variation in artery dimension during pulsatile flow; and to obtain a stroke-volume measurement of cardiac output.

A large number of patients who require continuous measurement of cardiac output have significant associated clinical problems. Often such patients have multiple systems organ failure, overwhelming sepsis, significant trauma to many major organ systems, decompensated congestive

heart failure, or major myocardial infarction. Such patients often have an endotrachael tube in place because of such problems. For example, in patients having a major surgical procedure, use of general anesthesia requires the presence of an endotrachael tube for the maintenance of the patient's airway. In the case of patients having open heart surgery, an endotrachael tube is often in place for the night following surgery. Patients suffering major trauma are routinely intubated following significant thoracic trauma, significant head injury, or multiple abdominal injuries. Patients in multiple systems organ failure, septic shock, or hemorragic shock have endotracheal tubes in place to assist ventilation during acute decompensation and in the immediate resuscitation phase. Patients with significant burn injuries frequently require endotracheal intubation during initial resuscitation, for transportation to a burn center, and for thermal injury to the respitory system. Patients with decompensated congestive heart failure leading to pulmonary decompensation with pulmonary accumulation of fluid require endotracheal intubation. Such patients may have underlying myocardial infarction, cardiomyopathy, cardiac valvular disease, or chronic congestive heart failure. In many of these examples, stabilization of the cardiovascular system is a prerequisite for removal of the tracheal tube. Consequently, use of an endotracheal probe in accordance with the present invention represents no further invasion of any body cavity. Thus, in the case of patients already having a tracheal tube in place, as well as in patients in which no tracheal tube has been previously placed for other reasons, the method

of the present invention provides for measurement of cardiac output at optimum locations without major surgical procedure or invasion of a closed body system. No major body cavity not routinely in communication with the external environment is required. No major or minor surgical procedure is required. No indwelling foreign body is necessary in the vascular system, a major body cavity, or in a major organ. No dye or radioactive substance is necessary for the measurement to be performed, and no air emboli are introduced. Continuous monitoring is also possible.

Having thus described the method and apparatus of the invention the following is claimed.

Claims

1. A method for determining the volumetric rate of flow of blood in a major discharge artery, including the aorta and pulmonary artery of a mammalian heart, which comprises:

a. placing a sound transducer in proximity to the artery by passage into the trachea of the mammal,

b. transmitting ultrasound waves from the transducer toward the path of flow of blood in the artery,

c. receiving the ultrasound waves reflected by the blood,

d. measuring the average Doppler frequency difference between the transmitted waves and the reflected received waves,

e. measuring the cross-sectional size of the artery at the point of ultrasound reflection, and

f. determining the volumetric blood flow rate from such measurements.

2. The method of claim 1 wherein the ultrasound waves are generated from the transducer in a direction within the range of 10° - 80° with respect to the direction of the path of flow of the blood.

3. The method of claim 1 wherein the ultrasound waves are transmitted from and received by the same transducer.

4. The method of claim 1 wherein the mammal is a human.

5. The method of claim 1 wherein the measurement of the cross-sectional size of the artery at the point of ultrasound reflection is done by means of ultrasound wave reflection.

6. The method of claim 1 wherein the cross-sectional size of the artery at the point of ultrasound reflection is determined by placing a second sound transducer in the trachea in proximity to the artery, transmitting ultrasound waves from the second transducer toward the artery, receiving the ultrasound waves reflected by the distant wall of the artery, measuring the time elapsed from transmission to reception, and determining the cross-sectional size of the artery from such measurements.

7. The method of claim 6 wherein the ultrasound waves from the second transducer are transmitted in a direction 90° with respect to the wall of the artery.

8. The method of claim 7 wherein the ultrasound waves from the transducer are transmitted in a direction about 45° with respect to and intersecting the transmission of ultrasound waves from the second transducer, and the distance between transducers is equal to the estimated radius of the artery at the point of ultrasound reflection.

9. A method for determining the volumetric rate of flow of blood in the ascending aorta of a human heart, which comprises:

a. placing a sound transducer in proximity to the ascending aorta by passage into the trachea,

b. transmitting ultrasound waves from the transducer toward the path of flow of blood in the aorta in a direction within the range of 10° - 80° with respect to the direction of the path of flow,

c. receiving the ultrasound waves reflected by the blood,

d. measuring the average Doppler frequency

difference between the transmitted waves and the reflected waves,

e. measuring the cross-sectional size of the aorta at the point of ultrasound reflection, and

f. determining the volumetric blood flow rate from such measurements.

10. The method of claim 9 wherein the ultrasound waves are transmitted from and received by the same transducer.

11. The method of claim 10 wherein the measurement of the cross-sectional size of the artery at the point of ultrasound reflection is done by means of ultrasound wave reflection.

12. The method of claim 11 wherein the cross-sectional size of the artery at the point of ultrasound reflection is determined by placing a second sound transducer in the trachea in proximity to the artery, transmitting ultrasound waves from the second transducer toward the artery, receiving the ultrasound waves reflected by the distant wall of the artery, measuring the time elapsed from transmission to reception, and determining the crosssectional size of the artery from such measurements.

13. The method of claim 12 wherein the ultrasound waves from the second transducer are transmitted in a direction 90° with respect to the wall of the artery.

14. The method of claim 13 wherein the ultrasound waves from the transducer are transmitted in a direction about 45° with respect to and intersecting the transmission of ultrasound waves from the second transducer, and the distance between transducers is equal to the estimated radius of the artery at the point of ultrasound

reflection.

15. A tracheal probe for use in determining blood flow rate in a major discharge artery, including the pulmonary artery and the aorta, of a mammalian heart, which comprises:

a. a flexible tube having a length sufficient to extend from the oral or nasal cavity of the mammal or from a surgical tracheal opening through the trachea to the bifurcation thereof, and

b. a first ultrasound transducer mounted to the tube in proximity to the end thereof and disposed to transmit in a direction within the range of 10° - 80° with respect to the axis of the tube.

16. The tracheal probe of claim 15 and a second ultrasound transducer mounted to the tube in proximity to the end thereof and spaced from the first transducer in the direction of ultrasound transmission from the first transducer and disposed to transmit in a direction of 90° with respect to the axis of the probe and intersecting the transmissions of the first transducer.

17. The tracheal probe of claim 16 wherein the distance from the first transducer to the second transducer is the estimated diameter of the artery at the point of intended measurement of blood flow, divided by twice the tangent of the angle of the direction of transmission from the first transducer with respect to the axis of the tube.

18. The tracheal probe of claim 16 wherein the first and second transducers are mounted in the tube.

19. The tracheal probe of claim 16 and electrical conductors extending respectively

from the first and second transducers the length of the probe.

20. The tracheal probe of claim 18 and electrical conductors extending respectively from the first and second transducers the length of the probe through the interior thereof.

Fig. 1

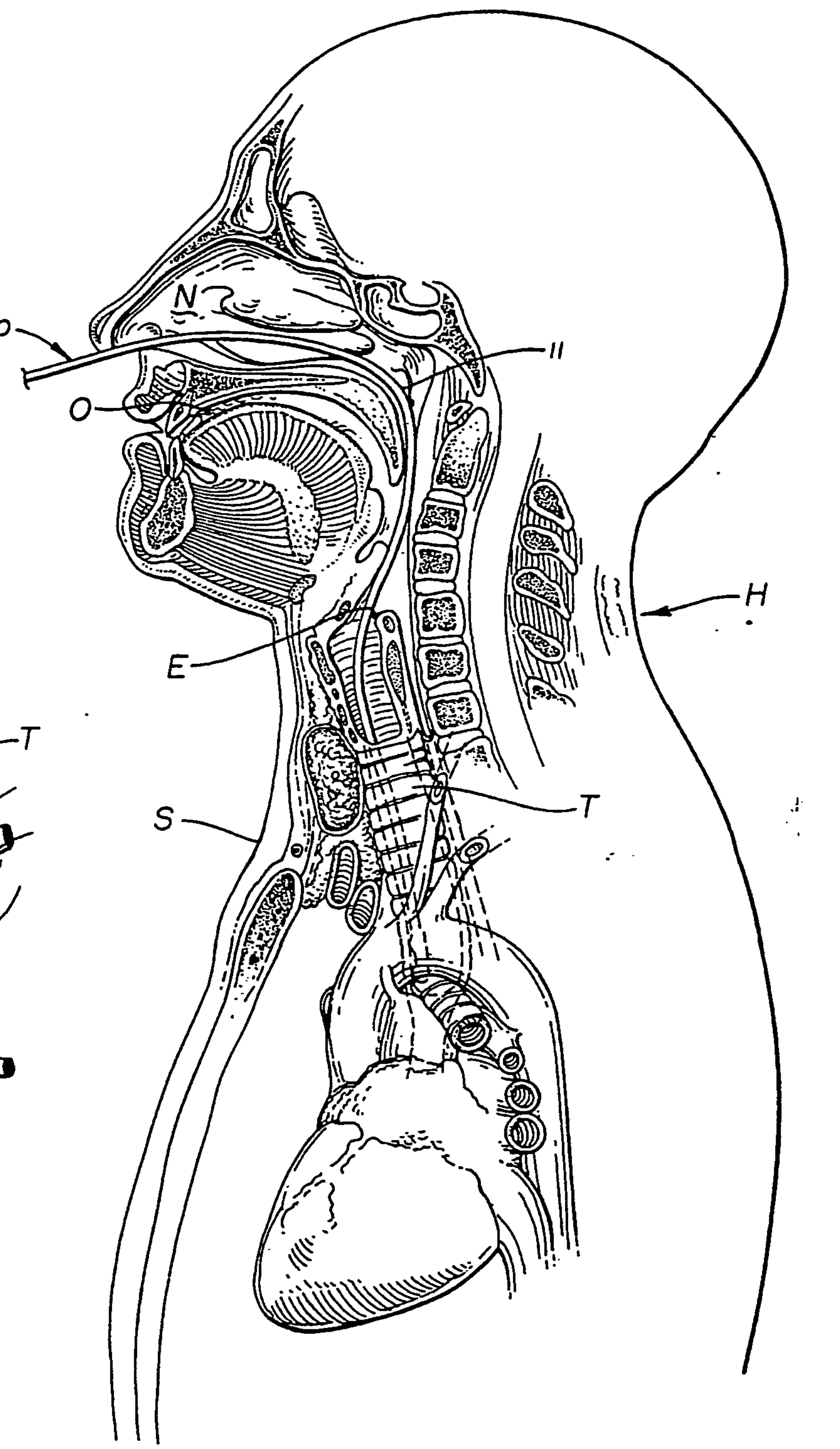


Fig. 2

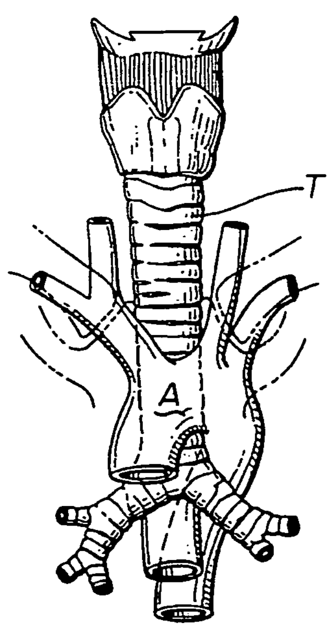


Fig 3

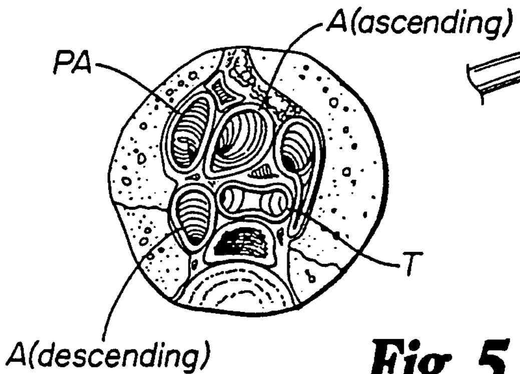


Fig 4

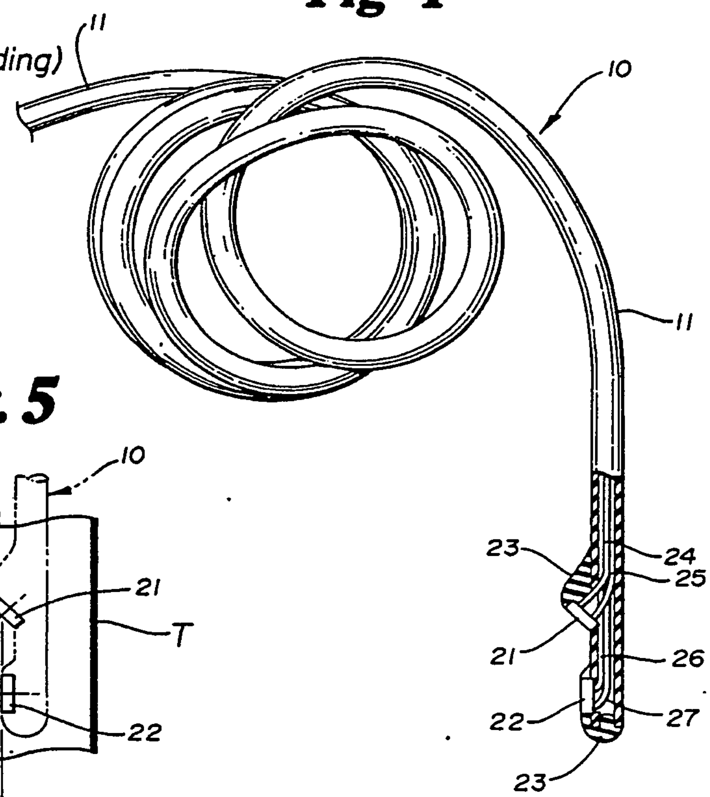


Fig. 5

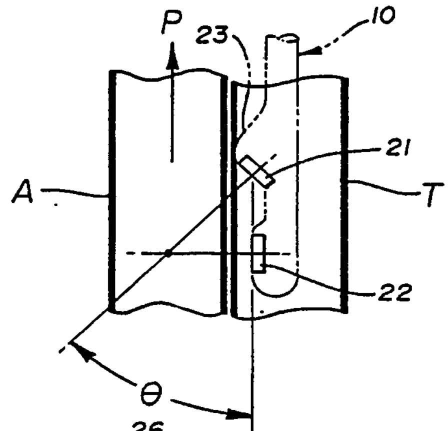
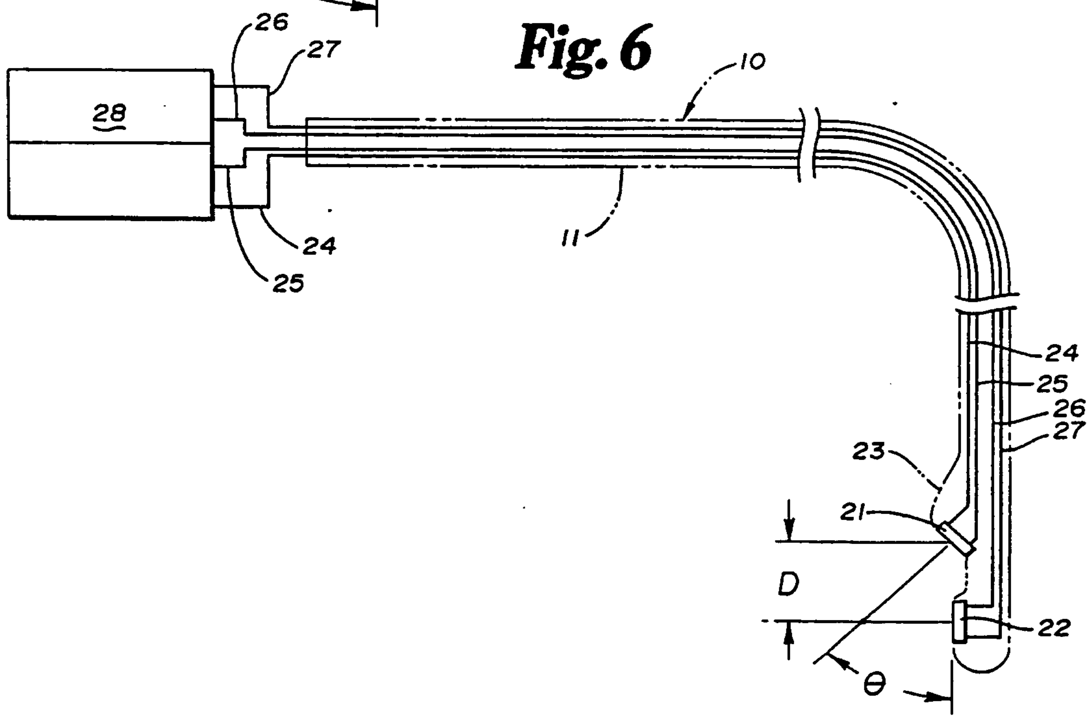


Fig. 6



INTERNATIONAL SEARCH REPORT

International Application No PCT/US86/00060

I. CLASSIFICATI N F SUBJECT MATTER (if several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int. Cl.[4] A61 B 10/00 U.S. Cl. 128/663

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
U.S.	128/661, 663, 713 73/861.25

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [5]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No. [18]
X,Y	Ultrasonics, September 1979, Histand et al, "Ultrasonic Pulsed Doppler Transesophageal Measurement of Aortic Haemodynamics in Humans"	8, 14-20
Y	US, A, 3,498,290, 03 March 1970, Shaw et al	1-7, 9-13, 17
Y	IEEE Transactions on Biomedical Engineering, Vol. BME - 21 No. 2 March 1974, Olson et al "A Nondestructive Ultrasonic Technique To Measure Diameter and Blood Flow in Arteries" p. 168-71.	1-7, 9-13
Y	US, A, RE 31377, 13 September 1983, Mylrea	1-7, 9-13
Y	Advances In Bioengineering, San Francisco, CA. 10-15 December 1978, Wells et al, "Ultrasonic Transesophageal Measurement of Cardiac Output" pp. 121-123.	8, 14
Y	IEEE Transactions On Sonics and Ultrasonics, Vol. SU-27 No. 6 November 1980, Martin et al.	1, 3-7

* Special categories of cited documents: [15]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search [2]	Date of Mailing of this International Search Report [2]
04 January 1986	21 FEB 1986
International Searching Authority [1]	Signature of Authorized Officer [10]
ISA/US	Ruth Smith

Form PCT/ISA/210 (second sheet) (ctober 1981)

International Application No. PCT/US86/00060

III. DOCUMENTS CONSIDERED TO BE RELEVANT (C NTINUED FR M THE SEC ND SHEET)		
Category*	Citation of Document,[16] with indication, where appropriate, of the relevant passages[17]	Relevant to Claim No[18]
	"An Ultrasonic Catheter for Intravascular Measurement of Blood Flow" pp. 277-286	1, 9, 15
A	US, A, 4,369,794, 25 January 1983, Furler	
A	US, A, 4,509,526, 09 April 1985 Barnes et al	1, 9
A	US, A, 4,370,985, 01 February 1983 Takeichi et al	1, 9
A	IEEE Transactions on Sonics and Ultrasonics, Vol. SU-17 No. 3 July 1970, Baker, pp. 170-184 "Pulsed Ultrasonic Doppler Blood-Flow Sensing"	1, 9
A	Ultrasound in Med & Biol. Vol. 11, No. 3 August 1974; Duck et al, "An Esophageal Doppler Probe for Aortic Flow Velocity Monitoring	1, 9, 15